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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,297

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Yusuke Nakamura

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EXAMINER

AEDER, SEAN E

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

02/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/573,297

Applicant(s)

NAKAMURA ET AL.

Examiner

Sean E. Aeder

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,23,25,28,60,63,83 and 84 is/are pending in the application.
- 4a) Of the above claim(s) 60,63,83 and 84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,23,25 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/26/06; 1/18/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Detailed Action

The Election filed 11/26/07 in response to the Office Action of 9/25/07 is acknowledged and has been entered. Applicant elected group III and the species "BRC 456" without traverse.

Claims 20, 23, 25, 28, 60, 63, 83, and 84 are pending.

Claims 60, 63, 83, and 84 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention. Note that claims 60, 63, 83, and 84 are not drawn to the elected species.

Claims 20, 23, 25, and 28 are currently under consideration.

Specification

The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (pages 32 and 46, in particular). Applicant is required to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumoto et al (Biochemical and Biophysical Research Communications, December 2004, 325:997-1004).

Claim 20 encompasses a method of screening for a compound for treating or preventing breast cancer, said method comprising the steps of: a) contacting a test compound with a polypeptide encoded by BRC 456; b) detecting the binding activity between the polypeptide and the test compound; and c) selecting the test compound that binds to the polypeptide. Claim 25 is drawn to the method of claim 20, wherein said breast cancer is IDC. The instant specification teaches that the BRC 456 encodes TOPK (see page 83, in particular).

It is noted that recitation of "a method of screening for a compound for treating or preventing breast cancer" is found in the preamble of claim 20 and "the method of claim 20, wherein said breast cancer is IDC" is found in the preamble of claim 25. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness, but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Therefore, a teaching that a selected "test compound" treats or prevents any type of breast cancer is not required to anticipate the pending claims.

Matsumoto et al teaches a method comprising the steps of: a) contacting a test compound with a polypeptide encoded by BRC 456 (TOPK); b) detecting the binding activity between the polypeptide and the test compound; and c) selecting the test compound that binds to the polypeptide (see Figure 2 and right column of page 998, in particular).

Claims 23 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldsworthy et al (US 2005/0064402 A1; filed October 1, 2001).

Claim 23 encompasses a method of screening for a compound for treating or preventing breast cancer, said method comprising the steps of: a) contacting a test compound with a polypeptide encoded by BRC 456; b) detecting the biological activity of the polypeptide of step "(a)"; and c) selecting the test compound that suppresses the biological activity of the polypeptide encoded by BRC 456 as compared to the biological activity of said polypeptide in the absence of the test compound. Claim 28 is drawn to the method of claim 23, wherein said breast cancer is IDC. The instant specification teaches that the BRC 456 encodes TOPK (see page 83, in particular).

It is noted that recitation of "a method of screening for a compound for treating or preventing breast cancer" is found in the preamble of claim 23 and "the method of claim 23, wherein said breast cancer is IDC" is found in the preamble of claim 28. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a

process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness, but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Therefore, a teaching that a selected "test compound" treats or prevents any type of breast cancer is not required to anticipate the pending claims.

Goldsworthy et al BRC 456 (TOPK, a.k.a. "PBK") is a kinase that is useful as a tumor marker (see paragraph 22, in particular). Goldsworthy et al further teaches a method comprising a) contacting a test compound with a polypeptide encoded by BRC 456; b) detecting the biological activity of the polypeptide of step "(a)"; and c) selecting the test compound that suppresses the biological activity of the polypeptide encoded by BRC 456 as compared to the biological activity of said polypeptide in the absence of the test compound (see paragraph 11 and claim 22, in particular). It is further noted that Goldsworthy et al further teaches that potential inhibitors to be used in said method include antibodies to TOPK (see paragraph 67, in particular).

Summary

No claim is allowed.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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